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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,293	10/05/2004	Kiyoharu Oono	2144.0220000/RWE/RAS	9002

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,293	OONO ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 7* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The rejections under 35 U.S.C. 102(b) are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandecki et al (U.S. Patent 6,046,003) in view of Akram et al (U.S. Patent 6,250,192).

Mandecki teaches a method for producing a labeled nucleic acid (e.g., fluorescently-labeled target DNA bound to probe attached to the surface of the transponder), wherein the

method comprises binding the nucleic acid (e.g., oligonucleotides) to a large scale integrated circuit (e.g., solid phase particles having a transponder associated with each particle), and recording specific
information (e.g., the sequence of the oligonucleotide) on the large scale integrated circuit (column 1, lines 55 - column 2, line 6, column 17, lines 28-44).

With regard to claim 3, Mandecki teaches a method wherein a substrate (e.g.. monoisocyanate) mediates the binding of a nucleic acid to the large scale integrated circuit (column 8, lines 21-45).

With regard to claim 7, Mandecki teaches recording specific information (e.g., the sequence of the oligonucleotide) on the large scale integrated circuit (column 1, lines 55 - column 2, line 6, column 17, lines 28-44).

Mandecki does not teach the use of integrated circuits with 320 million bits of memory (equivalent to 40 million bytes or 40 megabytes of memory).

Akram teaches the use of RFID integrated circuits with a capacity of 64 megabytes (see column 2, lines 1-15, especially line 9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the Mandecki device to use larger integrated circuits since Mandecki expressly notes "The present invention can be practiced with different transponders, which might be of different dimensions and have different electronic memory capacity (see column 5, lines 57-60)." Akram teaches that "It may,

however, be desirable to design and fabricate a semiconductor wafer having various integrated circuits and other semiconductor devices thereon, each of which may be of a different size. For example, in radio-frequency ID (RFID) applications, a battery, chip and antenna could be incorporated into the same wafer such that all semiconductor devices of an RFID electronic device are fabricated from a single semiconductor wafer. Alternatively, memory dice of

different capacities, for example, 4, 16 and 64 megabyte DRAMs, might be fabricated on a single wafer to maximize the use of silicon "real estate" and reduce thiefage or waste of material near the periphery of the almost-circular (but for the flat) wafer (see column 2, lines 1-13)."

An ordinary practitioner, motivated by Mandecki to utilize different RFID transponders with different sizes and memory capacities, would have been motivated to use the RFID devices of Akram with 64 megabytes when performing the method on complex samples where the number of variants exceeds 320 million. Mandecki exemplifies a three base situation where there are sixty four different possibilities (see example 2). A situation where more than 320 million possibilities would occur would only require a situation of analyzing a 15 nucleotide variable region, since 4^{15} equals a little over 1 trillion different possibilities. The ordinary practitioner would therefore be motivated to utilize the RFID device of Akram in the method of Mandecki when the oligonucleotide to be analyzed varied in 15 nucleotides or more in order to permit analysis of all of the possibilities.

5. Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent 5,741,462) in view of Akram et al (U.S. Patent 6,250,192).

Nova teaches a method for producing a labeled protein or gene (see abstract), wherein the method comprises binding the protein to a large scale integrated circuit (see column 29, line 45 to column 30, line 14, where antibodies are bound to the integrated circuit), and recording specific information that is characteristic of the peptide (see column 29, lines 50-55 where each antibody "is given a specific identification tag") on the large scale integrated circuit (see columns 29 and 30).

With regard to claim 3, Nova teaches a method wherein the peptide is bound to the large scale integrated circuit via a linker (see column 18, line 10, for example).

With regard to claim 5, Nova teaches an antibody mediates binding of a protein to the integrated circuit (see columns 29-30).

With regard to claim 7, Nova teaches recording specific information that is characteristic of the peptide (see column 29, lines 50-55 where each antibody "is given a specific identification tag")

Nova does not teach the use of integrated circuits with 320 million bits of memory (equivalent to 40 million bytes or 40 megabytes of memory).

Akram teaches the use of RFID integrated circuits with a capacity of 64 megabytes (see column 2, lines 1-15, especially line 9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the Nova device to use larger integrated circuits since Nova expressly notes "Based on current semiconductor integrated circuit fabrication process capabilities, in a preferred embodiment the finished chip on which all of the listed components are integrated is on the order of 1 mm.times.1 mm [.about.40 mils.times.40 mils], with a memory capacity of 1024 bits. Greater memory capacity, where needed, and smaller chips, however, will be preferred. The chip may be larger to accommodate more memory if desired, or may be smaller as design rules permit smaller transistors and higher device densities (see column 21, lines 8-16)." Akram teaches that "It may, however, be desirable to design and fabricate a semiconductor wafer having various integrated circuits and other semiconductor devices thereon, each of which may be of a different size. For example, in radio-frequency ID (RFID) applications, a battery, chip and antenna could be incorporated into the same wafer such that all semiconductor devices of an RFID electronic device are fabricated from a single semiconductor wafer. Alternatively, memory dice of different capacities, for example, 4, 16 and 64 megabyte DRAMs, might be fabricated on a single wafer to maximize the use of silicon "real estate" and reduce thiefage or waste of material near the periphery of the almost-circular (but for the flat) wafer (see column 2, lines 1-13)."

An ordinary practitioner, motivated by Nova to utilize different integrated circuits with greater memory capacity where needed, would have been motivated to use the RFID devices of Akram with 64 megabytes when performing the method on complex samples where the number of variants exceeds 320 million. A situation where more

than 320 million possibilities would occur would only require a situation of analyzing a 15 nucleotide variable region, since 4^{15} equals a little over 1 trillion different possibilities. The ordinary practitioner would therefore be motivated to utilize the RFID device of Akram in the method of Nova when the oligonucleotide to be analyzed varied in 15 nucleotides or more in order to permit analysis of all of the possibilities.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandecki et al (U.S. Patent 6,046,003) in view of Akram et al (U.S. Patent 6,250,192) and further in view of Stavrianopoulos et al (U.S. Patent 4,994,373).

Mandecki in view of Akram teach the limitations of claims 1, 3 and 7 as discussed above.

Mandecki does not teach the specific substrates of claim 4.

Stavrianopoulos teaches attachment of nucleic acids to plastic matrices (see column 12, lines 5-15, for example).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the epoxy resin of Stavrianopoulos to attach the nucleic acids of Mandecki in view of Akram since Stavrianopoulos notes "An improved capability for fixing or immobilization of DNA to non-porous siliceous solid supports, such as glass and plastic, is also provided by treatment with a coating of an epoxy

resin. (see column 12, lines 5-15)". An ordinary practitioner would have been motivated to use the epoxy resin of Stavrianopoulos in order to improve the ability of the DNA to be fixed to the plastic solid supports of Mandecki as expressly suggested by Stavrianopoulos.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al (U.S. Patent 5,741,462) in view of Akram and further in view of Stavrianopoulos et al (U.S. Patent 4,994,373).

Nova in view of Akram teach the limitations of claims 1, 3, 5 and 7 as discussed above.

Nova teaches a variety of synthetic plastic matrices as substrates at column 17, but Nova does not teach the specific substrates of claim 4.

Stavrianopoulos teaches attachment of nucleic acids to plastic matrices such as those of Nova using epoxy resin (see column 12, lines 5-15, for example).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the epoxy resin of Stavrianopoulos to attach the nucleic acids or proteins of Nova in view of Akram since Stavrianopoulos notes "An improved capability for fixing or immobilization of DNA to non-porous siliceous solid supports, such as glass and plastic, is also provided by treatment with a coating of an epoxy resin. (see column 12, lines 5-15)". An ordinary practitioner would have been motivated to use the epoxy resin of Stavrianopoulos in order to improve the ability of the

DNA to be fixed to the plastic solid supports of Nova as expressly suggested by Stavrianopoulos.

Allowable Subject Matter

8. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: Claim 6 is drawn to an embodiment with two differences from claim 1, a requirement that the protein is attached to the integrated circuit via the sugar chain and a requirement that some information regarding the sugar chain is encoded on the integrated circuit. While Keogh does teach attachment of proteins to supports via sugar chains, Keogh does not suggest encoding this information onto an integrated circuit. While Mandecki teaches encoding the sequence of the nucleic acid onto the circuit, there is no suggestion to encode the linker information, to which the sugar in claim 6 corresponds. Therefore, there is no suggestion in the prior art to both attach a protein by a sugar chain and encode the sugar chain information onto the integrated circuit.

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
7/6/06